



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

In Reply Refer To: 13B

VA influenza vaccine update – October 17, 2003

This message is to update you with respect to the influenza vaccine campaign in VA.

Flu vaccination: A VA priority

Vaccination of staff and patients against influenza remains a VA priority. Earlier this month, Dr. Roswell signed *VHA Directive 2003-058, Influenza Vaccine – Recommendations for 2003-2004* outlining the importance of influenza vaccination for VA employees and patients and providing details about the 2003-2004 campaign. Recently, we have been made aware of concerns about the safety of the VA influenza vaccine supply and this update will provide information about that.

Reports of possible adverse reactions to influenza vaccination in VA

The week of October 13, Central Office received three reports of possible adverse reactions associated with the influenza vaccine administered by VA. Such reports are also sent to the Vaccine Adverse Event Reporting System (VAERS), a federal vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). The reports were also sent to the manufacturer of the VA supply of influenza vaccine, Aventis Pasteur.

The three reports, two from one VAMC and one from another described three different situations in persons receiving flu shots. One situation involved skin redness, neck and face swelling, throat tightness and shortness of breath within minutes of the shot—symptoms typical of an allergic or hypersensitivity reaction. The individual was treated, recovered and is doing well. A second situation involved skin redness, difficulty breathing, and malaise within a few hours after the shot. This individual was later diagnosed with pneumonia, possibly as a consequence of pre-existing chronic illness. This employee remains hospitalized. In a third situation, an individual was undergoing treatment for a sinus infection at the time of vaccination and experienced shortness of breath a few hours after receiving the shot, had no additional symptoms, and no treatment and is now better. This reaction is not a typical allergic or hypersensitivity type reaction, but we are including it in our consideration of these events in order to be careful and thorough.

Reactions are within the normal, expected events

A team of VA staff in public health, occupational health, infectious disease, pharmacy, the network office, and others has examined these reports and is also in communication with clinical scientists from FDA, CDC, and Aventis Pasteur. The team believes that these reactions are all within the range of possible—but still very rare—reactions that can occur with influenza vaccination. In addition, Aventis Pasteur has reviewed all of its production, testing, and surveillance records on the lot of vaccine supplied to VA and found no reason for concern in any of these reports. Neither Aventis Pasteur nor the VAERS system have received other reports of unusual adverse reactions to this lot of influenza vaccine. Furthermore, FDA has reviewed the reported information and has indicated to us that they do not intend to issue a drug recall. **The lot of vaccine involved, which was initially quarantined by VA a few days ago, has now been released for use again in the VA system.**

Finally, members of the VA team examining the information also said that they would get a flu shot today if it were available in Central Office (supplies will be in around the end of October).

(more)

Continued monitoring and additional information

VA, in concert with CDC, FDA, and the manufacturers of influenza vaccine products all have systems in place to keep track of any unusual or serious reactions that might occur subsequent to vaccination. There are well-established processes to monitor, report, and investigate possible reactions. The reporting of these recent events shows that VA's system is operating properly and supports continued protection of both veteran and employee health and safety. There is also a great deal of information available about influenza, the influenza vaccine, and its safety.

Key information sites to note:

For reporting reactions and information on the process:

--VAERS (Vaccine Adverse Event Reporting System) at 800-822-7967 (the Web site is www.vaers.org). Facilities should also notify their VISN director, who will forward any information to Central Office. In addition, Aventis Pasteur, the manufacturer of VA's influenza vaccine supply, would like reports on any unusual or serious reactions and is providing a phone number for reports and questions: 800-822-2463 (1 800-vaccine).

For information on influenza and influenza vaccination:

-- From CDC: the main flu program page is <http://www.cdc.gov/nip/Flu/default.htm>

For vaccine information from FDA:

-- <http://www.fda.gov/cber/vaccines.htm>

For VA's 2003-2004 Flu Toolkit:

<http://vaww.nchpdp.med.va.gov/0304FluPneumoToolkit.pdf>

For information on emerging public health issues, see the new VA Web site Public Health Watch at

<http://www.publichealth.va.gov/watch/>

Balance of risk – flu vaccine is much safer than getting the flu

The flu: Influenza or flu is a serious, contagious, preventable illness. It occurs in millions of Americans each year, causing in most a week or two of illness, but leading to hospitalization and life-threatening complications in some. Influenza is the cause of death of approximately 36,000 Americans each year. Serious problems from influenza can occur at any age, although those who are older than 65, or very young and those with chronic medical conditions are most vulnerable to flu's complications. People who develop the flu then put their family, friends, coworkers and patients (if they are health care workers) at risk of the disease.

The vaccine: Because the flu vaccine contains only noninfectious viral particles, it cannot cause the flu. The risks are as follows:

--As with many vaccinations, there is often soreness at the injection site.

--Respiratory disease that occurs after a flu shot is a coincidence and not unexpected in some people when thousands are being vaccinated.

--Systemic reactions to vaccination are known to occur and can be of two major types: a) Occasional fever, malaise, feeling achy, and similar symptoms; and b) Rare allergic or hypersensitivity reactions that are most likely in reaction to some component of the vaccine.

Again, these events are known to occur and are not unexpected when thousands of people are being vaccinated.

The benefit to public health by influenza immunization programs far outweighs the risk of these rare reactions and is the basis of CDC and VA's strong proactive influenza immunization programs.

VA is careful about the health of our patients and our staff and our message remains: Get your flu shot today. Protect yourself, your family, friends, colleagues and patients or others that you serve, and stay well so you can help veterans.

Note: we issued a letter 2 weeks ago recommending the use of flu shots and avoidance of the new nasal spray form of the vaccine. This new form presents a risk to immunosuppressed individuals who are near vaccinees for 3 weeks after administration. We urge VA staff to get flu shots, which are available for free from VA, and avoid the nasal form that may be available in the community.

Office of Public Health and Environmental Hazards (13)
Public Health Strategic Health Care Group
Occupational Safety and Health Program